United States Court of Appeals

for the Second Circuit

BRIEF FOR APPELLEE

Original with Affidavit of Mailing

76-1398

To be argued by
CYRIL HYMAN

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 76-1398

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

—*against*—

DIAPULSE CORPORATION OF AMERICA, also known as the DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation, JESSE ROSS, president of the corporation, and JOSEPH I. ROSS, vice-president and treasurer of the corporation,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF FOR PLAINTIFF-APPELLEE

UNITED STATES COURT OF APPEALS FILED NOV 15 1976 A. DANIEL FUSARO, CLERK SECOND CIRCUIT

ALVIN A. SCHALL
CYRIL HYMAN
Assistant United States Attorneys

RICHARD A. MERRILL
Chief Counsel

FORREST T. PATERSON
Associate Chief Counsel

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

DONALD I. BAKER
Assistant Attorney General
Antitrust Division

DAVID G. TRAGER,
United States Attorney
Eastern District of New York

CHARLES R. McCONACHIE
Acting Chief
Consumer Affairs Section

JOHN FLEDER
Attorney
Consumer Affairs Section

United States Department of Justice
Washington, D.C. 20530

TABLE OF CONTENTS

TABLE OF CITATIONS

Cases:

PAGE

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 76-1398

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

—against—

DIAPULSE CORPORATION OF AMERICA, also known as the DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation, JESSE ROSS, president of the corporation, and JOSEPH I. ROSS, vice-president and treasurer of the corporation,

Defendants-Appellants.

BRIEF FOR PLAINTIFF-APPELLEE

Preliminary Statement

Diapulse Corporation of America and Jesse Ross, its president, and Joseph I. Ross, its vice-president and treasurer, appeal from judgments of the United States District Court for the Eastern District of New York (Dooling, *J.*), entered on August 30, 1976, convicting them, after a jury trial, of criminal contempt for violating certain terms of a permanent injunction order dated July 18, 1974, in violation of Title 18, United States Code, Section 401. Appellant Jesse Ross was convicted of one count of violating the injunction and was fined $2,500. The corporation was found guilty of two counts

of violating the injunction and was fined $1,250 on each count, for a total of $2,500. Appellant Joseph I. Ross was also convicted of two counts of violating the injunction. He was fined $625 on each count, for a total of $1,250. Execution of the sentence of each appellant has been stayed pending this appeal.[1]

Appellants' appeals present three issues for resolution by this Court.

1. Whether the evidence established that the defendants, in violation of an injunction, refused to allow duly authorized Food and Drug Administration investigators to conduct inspections authorized by the injunction.

2. Whether the district court improperly admitted allegedly prejudicial evidence over the defendants' objections.

3. Whether the sentence imposed upon the defendants amounts to an abuse of discretion by the district court.

Statement of the Case

The corporate defendant, Diapulse Corporation of America, is a Delaware corporation, with its principal place of business located in New Hyde Park, New York. It manufactures and markets an electromagnetic generator similar to a conventional diathermy unit but with a lower output, intended to create a unique athermal effect. The machine is called the "Diapulse". The Diapulse has been marketed with claims that it will help a wide range of medical problems. As noted above, Mr. Jesse Ross is the president of the corporation, while Mr. Joseph Ross is the vice-president and treasurer of the corporation.

---

[1] One count of the contempt petition was dismissed by the district court on April 28, 1976, before the case went to trial.

1. The injunction.

In April 1968, the Government instituted an action for an injunction pursuant to the injunctive provisions of the Federal Food, Drug, adn Cosmetic Act (the Food and Drug Act), 21 U.S.C. § 332, in the Eastern District of New York, to restrain the distribution of the Diapulse device accompanied by false and misleading claims. Trial commenced in June 1971. During the course of that trial, on the Government's motion, a preliminary injunction was entered by the district court (the late Judge George Rosling). That preliminary injunction was affirmed by this Court on March 20, 1972. *United States* v. *Diapulse Corporation of America*, 457 F.2d 25 (2d Cir. 1972).

On July 18, 1972, a permanent injunction was entered by Judge Rosling prohibiting, the Diapulse Corporation of America from, among other things, shipping the misbranded Diapulse in interstate commerce. That injunction was affirmed by this Court without opinion. *United States* v. *Diapulse Corporation of America*, 485 F.2d 677 (2d Cir. 1973), *cert. denied*, 416 U.S. 938 (1974).

Subsequently, a contempt action alleging violations of both the preliminary and permanent injunctions was instituted on April 12, 1974.[2] That action was dismissed by United States District Judge John F. Dooling, Jr., on the grounds that the Government had failed to show a criminal intent to circumvent the injunctions. Subsequent to that ruling, however, Judge Dooling continued to hear evidence on cross-motions by the parties for modification of the permanent injunction entered July 18, 1972. On July 18, 1974, Judge Dooling entered an

---

[2] The preliminary injunction was alleged to have been violated by the shipment of a modified Diapulse device known as the "P/Emf". The permanent injunction was alleged to have been violated by the shipment of components for the modification of misbranded Diapulse devices previously shipped.

injunction more comprehensive and specific than the one previously in effect. That injunction was affirmed by this Court on March 21, 1975. *United States* v. *Diapulse Corporation of America*, 514 F.2d 1097 (2d Cir.), *cert. denied*, — U.S. —, 96 S.Ct. 66 (1975).

Section V(B) of the permanent injunction entered July 18, 1974, provides in pertinent part that (A-3):[3]

> The Defendant, Diapulse Corporation of America, a corporation, shall:
>
> * * * * *
>
> (b) grant duly authorized officers and employees of the Food and Drug Administration free access to any of its offices, plants, factories, warehouses, storage facilities, or other establishments at reasonable times during regular working hours, within reasonable limits and in a reasonable manner to inspect such establishment and all pertinent equipment, finished and unfinished materials, containers, and labeling therein; and such inspection may include copying and photographing and shall also extend to all things therein (including records, files, papers, processes, and facilities) bearing on whether any prohibited devices have been or are being manufactured, assembled, processed, packed, transported, or held in such place.

2. Attempted inspection of October 7th, 1975.

FDA Investigator Murray L. Kurzman testified that on October 7, 1975, he and FDA investigator Harry R. Baukney visited the premises of the Diapulse Corporation at 4 Nevada Drive, Lake Success, New Hyde Park, New York, for the purposes of attempting to conduct an inspection as authorized by the injunction (A-105-107;

---

[3] "A" references are to pages of Appellants' Appendix.

Tr. 26-28).[4] Upon arrival at the firm, the investigators were advised that the president of the firm, Jesse Ross, was not present but that another official, Joseph Ross, would arrive later (A-109-12; Tr. 29-33).

When Joseph Ross arrived, he identified himself to the investigators and advised them that he was the vice-president and treasurer of the firm (A-109-110; Tr. 30-31). The investigators presented to Mr. Ross the credentials which had been issued to them by the Food and Drug Administration authorizing them to conduct inspections (A-110-111; Tr. 31-32). The investigators' credentials consisted of two cards, FD Forms 200 A and 200 C, which include photographs of the investigators to whom they are issued and a statement of the investigators' authority (A-130-133; Tr. 51-55). The credentials were introduced into evidence as defendants' exhibit A.[5]

The investigators also issued to Joseph Ross a notice of inspection. This notice consists of a form reciting the authority for inspection under the statutes administered by the Food and Drug Administration and informing the person to be inspected of the date and time of inspection, the identity of the investigators, and the FDA district office involved (A-13).

Joseph Ross was advised that the investigators were there to inspect the physical premises as well as production and sales records of the Diapulse Corporation from the date of the injunction which had gone into effect in July 1972, and the investigators asked to see the firm's records concerning Diapulse and P EmF devices (A-112; Tr. 33). In response, the investigators were advised by

---

[4] "Tr." references are to the trial transcript.

[5] The authorization provided by these credentials is discussed in detail Point I, *infra*.

Joseph Ross that he would have to defer permission for the inspection until Jesse Ross was available and that he (Jesse Ross) would probably be present the following Wednesday, October 15.

The investigators also asked to see other records in the possession of the firm, including records concerning the recall provision of the injunction and records concerning devices that had been returned pursuant to the recall provision of the injunction (A-115-17; Tr. 38).[6] Joseph Ross also refused permission to inspect these records. The investigators again asked to see production and sales records from the date of the injunction which had gone into effect in July 1972, and Joseph Ross again refused to produce these records, stating that this would require a decision by Jesse Ross (A-119; Tr. 40).

Following Joseph Ross' refusal to permit inspection, as explained above, investigator Kurzman read to Joseph Ross from a copy of the injunction Section V(B) authorizing inspection (A-120; Tr. 41). Following the reading of that provision of the injunction to Joseph Ross, investigator Kurzman also advised Joseph Ross that there was no provision of that section requiring that Jesse Ross be present at the time of the inspection (A-120-121; Tr. 41-42). Joseph Ross, however, repeated that Jesse Ross' presence was necessary for the inspection to be conducted and refused to allow inspection of the firm's premises and records (A-121; Tr. 42).

---

[6] Paragraph IV(D) of the permanent injunction of July 18, 1974, included a provision requiring the Diapulse Corporation to notify persons who had modified Diapulse devices (P/EmF) to return such devices to the firm.

3. Attempted inspection of October 15th, 1975.

On October 15, 1975, investigators Baukney and Kurzman again visited the Diapulse Corporation for the purpose of attempting to conduct the inspection authorized by the injunction (A-122; Tr. 43). On this occasion, both Jesse Ross and Joseph Ross were present (A-123; Tr. 44). The investigators presented their credentials and issued a notice of inspection (A-14) to Jesse Ross as president of the firm (A-125, 137-138; Tr. 46, 58-59). The investigators requested, as duly authorized FDA representatives, to make an inspection of the Diapulse Corporation of America.

Jesse Ross refused to allow the inspection, stating that his firm was not manufacturing or introducing anything in interstate commerce and that therefore he had nothing to show the investigators (A-125, 143; Tr. 46, 64). The investigators indicated that the refusal to allow the inspection was in violation of the injunction (A-125, 154; Tr. 46-64). Joseph Ross stated that as far as he was concerned there was nothing on the premises that would be available to the investigators for inspection (A-127; Tr. 48).

Before leaving the premises, the investigators repeated their understanding that inspection was being refused (A-156; Tr. 71). In response, the defendant refused to allow inspection, stating that the firm had no records relating to inter-state commerce (A-150; Tr. 71).

The testimony of FDA investigator Kurzman was corroborated by FDA investigator Baukney (A-165-167; Tr. 86-88). Moreover, a tape recording taken by Jesse Ross during the attempted inspection of October 15, with the consent of the inspectors, provided a verbatim account of that attempted inspection (A-142; Tr. 63).

4. The Contempt

Pursuant to a petition for an order to show cause in criminal contempt filed by the Government on November 26, 1975, Judge Dooling ordered the defendants to show cause why they should not be punished for criminal contempt of the July 18, 1974, permanent injunction for refusing on three occasions to allow duly authorized Food and Drug Administration (FDA) employees to conduct inspections pursuant to Section V(B) of the permanent injunction (A-1).[7]

The defendants twice moved for dismissal, principally on the grounds that the FDA investigators who attempted to conduct the inspections were not "duly authorized . . . employees of the Food and Drug Administration" (A-15) and that the refused inspections were not attempted pursuant to the injunction (A-39-45). These motions were denied with respect to attempted inspections alleged to have been refused on October 7 and 15, but were granted with respect to an inspection alleged to have been refused on July 2, 1975 (A-19-24, A-46).

With respect to the attempted inspections of October 1975, the petition alleged that the defendants, Diapulse Corporation of America, and Jesse Ross, president and Joseph I. Ross, vice-president and treasurer of the corporation, at New Hyde Park, New York, refused to grant Food and Drug Investigators who were duly authorized employees of the Food and Drug Administration, access to the Diapulse Corporation establishment at 4 Nevada Drive, Lake Success, New Hyde Park, New York, at a reasonable time during regular working hours, to inspect the establishment and all the pertinent equipment,

---

[7] An inspection had been sought on July 2, 1975. The count pertaining to this charge was dismissed by Judge Dooling on April 28, 1976.

finished and unfinished materials, containers, and labeling therein and all things therein bearing on whether any prohibited devices, as defined by Section II(E) (A-3-4)[5] of the Order of Permanent Injunction were being manufactured, assembled, processed, packed, transported or held in the establishment.

In June 1976, the defendants were tried on these charges before Judge Dooling and a jury, and at the conclusion of said trial the jury returned a verdict of guilty against each defendant. On August 27, 1976, the defendant Jesse Ross was sentenced to a fine of $2500 for one count of violating the injunction; the defendant Joseph I. Ross was sentenced to a fine of $625 on each of two counts of violating the injunction, for a total fine of $1250; and the corporation was sentenced to a fine of $1250 on each of two counts of violating the injunction, for a total fine of $2500. Judgment of conviction was entered August 30, 1976, with execution of the sentence stayed pending appeal. On August 30, 1976, the defendants filed this appeal.

ARGUMENT

POINT I

The evidence established that appellants refused to allow duly authorized Food and Drug Administration investigators to conduct inspections authorized by the injunction.

The basis for appellants' convictions was their refusals to permit inspectors Kurzman and Baukney to

---

[5] Pursuant to Section II(E) of the injunction, the term "prohibited devices" includes the Diapulse device and a modified Diapulse device known as the P/EmF.

inspect the premises of the Diapulse Corporation on October 7th and October 15th 1975, in accordance with the provisions of Section V(B) of the permanent injunction of July 18, 1974. On appeal, appellants contend that their convictions should be reversed. The chief ground which they assert in support of their claim is the contention that investigators Kurzman and Baukney were not duly authorized to conduct the inspections which they attempted to conduct on October 7th and October 15th, 1975. Appellants further argue that even assuming the two investigators did have the requisite authority, they did not seek to inspect pursuant to the provisions of the injunction, as they were required to do, but rather sought to proceed under the general authorization granted to Food and Drug Administration investigators under Title 21, United States Code, Section 374. We respectfully submit that the record in this case clearly demonstrates that appellants' contentions are without merit.

1.

Under the terms of Section V(B) of the injunction, the persons who may conduct inspections are "duly authorized officers and employees of the Food and Drug Administration." Since the injunction itself does not provide any specific procedure for authorizing FDA officers and employees to conduct the inspection, we submit that the FDA employees who were duly authorized to conduct inspections provided for by the injunction were those persons specifically designated by the FDA to conduct inspections and investigations pursuant to the Agency's authority under 21 U.S.C. §§ 372 and 374(a).[9] Reliance by the Agency on its existing procedures for the

[9] Section 374 of Title 21 provides that duly designated "officers or employees" of the FDA may conduct inspections authorized in Section 372 of Title 21. Section 372 authorizes inspections for purposes of enforcing the Food and Drug Act.

authorization of employees to conduct the inspection contemplated by the injunction was clearly in accord with the holding of this Court that Section V(B) of the injunction does not exceed the inspectional authority provided under 21 U.S.C. § 374(a). *United States* v. *Diapulse Corporation of America*, *supra*, 514 F.2d 1097.

Pursuant to Section 374 of Title 21, authority regarding inspectional enforcement activities has been delegated to certain officers and employees of the FDA who are specifically qualified and to whom have been issued Food and Drug Administration official credentials consisting of FD Forms 200 A, B, and C. The authority of FDA employees to whom these official credentials have been issued are set out at 21 CFR 5.34 (formerly 21 CFR 2.121(p), recodified 41 FR 21262, June 15, 1976). As provided in pertinent part by 21 CFR 5.34(a)(1) and (b)(1), such employees are authorized:

> To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records; and to supervise compliance operations, for the enforcement of the Federal Food, Drug, and Cosmetic Act, . . .

As indicated above, the evidence establishes that the credentials carried by investigators Baukney and Kurzman were exhibited by them to the defendants at the time of the attempted inspections on October 7th and 15th, 1975. Investigators Baukney and Kurzman carried FD Form 200 A entitled "Identification Record" and FD Form 200 C entitled "Specification of General and Special Authority." The text of FD Form 200 C is as follows:

"DEPARTMENT OF HEALTH, EDUCATION
AND WELFARE"
PUBLIC HEALTH SERVICE
This certifies that

(the person named therein)

whose photograph appears below *is a duly accredited scientifically trained agent* specifically authorized to have access to and copy or verify any records and reports required under Section 505(i) or (j) or 507(d) or (g) of the Federal Food, Drug, and Comestic Act as amended *and is authorized to administer oaths and affirmations and to act for the Commissioner in the performance of the duties provided in the laws and Department Regulations administerd by the*

FOOD AND DRUG ADMINISTRATION.

No ..... Expires ..... A.M. SCHMIDT
Commissioner of
Food and drugs

[Emphasis supplied].

These credentials established that investigators Baukney and Kurzman were FDA employees to whom had been delegated the authority to conduct inspections for the FDA, as prescribed by 21 CFR 5.34. Pursuant to this authority, the investigators were "duly authorized" to conduct the inspection authorized by Section V(B) of the injunction.

Section V(B) of the 1974 injunction specifically authorizes inspection of, among other things, the facilities and records of the Diapulse Corporation. FDA investigators Baukney and Kurzman orally demanded to inspect the premises and records of the Diapulse Corporation on both October 7th and 15th, 1975. Since both Jesse Ross and Joseph I. Ross were fully aware of the inspection provi-

sion of the injunction (A-187, 259-261; Tr. 108, 177-80), this was sufficient notice to the defendants that inspection was being demanded pursuant to Section V(B) of the injunction.

When access to inspect was refused by the defendants, however, the investigators went further: Section V(B) of the injunction was read on October 7 to Joseph Ross, and both Joseph Ross and Jesse Ross were advised on October 15 that their refusal to alow inspection was regarded as a violation of the injunction. Indeed, Jesse Ross admitted on cross-examination that he had been advised by the FDA investigators during the October 15th inspection that his refusal to allow inspection was a violation of the injunction (A-221; Tr. 141). Accordingly, there can be no doubt that the defendants were well aware that their refusal to allow the demanded inspection was contrary to the terms of the injunction.

In addition to their oral demand to inspect, however, the investigators also issued a notice of inspection at each of the attempted inspections. A copy of the notice issued at the October 7th attempted inspection and the notice issued at the October 15th attempted inspection appears at pages 13 and 14 of the appellants' appendix. These notices are required by 21 U.S.C. § 374(a) for inspections conducted pursuant to the inspectional authority of the Food and Drug Act. Such notices were issued at the time of each of the attempted inspections involved in this case, because FDA investigators are required to issue such a notice each time they conduct an inspection, as here, for the enforcement of the Act, including inspections for the enforcement of injunctions issued under the Act.

On the basis of the foregoing facts appellants have sought to fashion their argument that the investigators were improperly operating under the provisions of Sec-

tion 374 rather than Section V(B) of the injunction. They contend that the oral demand to inspect under the authority of the injunction was contradicted by the notice of inspection which recited less specific inspectional authority, to wit: Section 374. Thus, appellants argue [Br., p. 29], in a seemingly sarcastic vein, that ". . . a criminal contempt was committed by the [defendants'] refusal to accept a totally unsupported oral assertion of authority in contradiction of the Government documents. . . ." This is incorrect, however, because the statutory language set out in the notice of inspection issued to the defendants does not contradict the provisions of Section V(B) of the injunction.

Section V(B) of the injunction is based on 21 U.S.C. 374(a), which provides general authority for inspections for the enforcement of the Food and Drug Act. [Compare 21 U.S.C. § 374(a) with Section V(B) of the injunction (A-3).] Section V(B) of the injunction, however, also provides more specific authority for the inspection of defendants' premises and records. The propriety of this close relationship between the statutory language and the injunctive provisions is illustrated by the decision in *United States* v. *Lit Drug Co.*, 333 F. Supp. 990, 996 (D. N.J., 1971), which points out that

> [O]ther courts in enforcing regulatory legislation, have used little more than a recitation of statutory language in wording injunctions and have not regarded this practice as offensive to Rule 65(b). *United States* v. *Hill* [298 F. Supp. 21, D. Conn., 1969]; *United States* v. *Schlicksup Drug Co.*, 206 F. Supp. (S.D. Ill., 1962); *United States* v. *Sherwood*, 175 F. Supp. 480 (S.D.N.Y., 1959) . . .

Since this Court specifically rejected the contention that the inspectional authority conferred by the injunction exceeds the inspectional authority of the Act, *United States*

v. *Diapulse Corporation of America, supra*, 514 F.2d 1097, the oral demand for access to inspect, as authorized by Section V(B) of the injunction, accompanied by the issuance of a notice of inspection pursuant to the authority of the Food and Drug Act was not inconsistent with Section V(B) of the injunction.[10]

POINT II

Evidence prejudicial to the appellants was not improperly admitted over appellants' objections.

Appellants contend [Br., p. 30, para. 5] that the district court improperly admitted, over their objections, allegedly prejudicial, inadmissible evidence. Significantly,

---

[10] We need only note in passing appellants' offhand suggestion (appellants' brief page 30) that the evidence at trial failed to establish that there had been criminal contempt.

Indeed, when the evidence set forth above is viewed in the light most favorable to the Government, as it must be, *Glasser* v. *United States*, 315 U.S. 60, 80 (1942); *In Re Joyce*, 506 F.2d 373, 376 (5th Cir. 1975); *Cf. United States* v. *Manton*, 107 F.2d 834, 839 (2d Cir. 1939), it is clear beyond a reasonable doubt that inspections authorized by the injunction were refused by the defendants on October 7 and 15, 1975. These refusals satisfied the requirements for contempt convictions as recognized by the courts. See *Gompers* v. *Bucks Stove & Range Co.*, 221 U.S. 418, 444 (1911); *Parker* v. *United States*, 153 F.2d 66, 70 (1st Cir. 1946).

Appellants appear to suggest, based on *In Re Brown*, 454 F.2d 999, 1007 (D.C. Cir. 1971), that evidence of specific intent is required to support a contempt conviction. However, the authority is clear that such proof is not required to establish contempt of an injunction issued pursuant to the Food and Drug Act. *United States* v. *Lil' Drug Co.*, 333 F. Supp. 990, 996-7 (D. N.J., 1971); *United States* v. *Schlicksup Drug Co., Inc.*, 206 F. Supp. 801, 804 (S.D. Ill., 1962). Nevertheless, the district court charged the jury that it had to find that the defendants refused the attempted inspections knowing that such refusal was in violation of the injunction (A-294-295).

appellants fail to identify what they refer to as the "errors implicit" in the admission of the evidence they specify. In any event, the contention is without merit.

Appellants first refer (Br., p. 14, first paragraph) to a teletype dated October, 1975, from FDA headquarters in Rockville, Maryland, to FDA's New York District Office requesting an inspection to determine Diapulse's compliance with the injunction. A copy of this telegram was supplied to appellants as part of the further bill of particulars (A-35). The document was offered into evidence as part of the Government's proof that the inspections were sought to be conducted pursuant to the authority of the injunction and was objected to on the ground that it had not been brought to the attention of appellants (A-104; Tr. 25). Because the document had, in fact, been turned over to the defense, the objection was overruled and the document was admitted into evidence (A-104;; Tr. 25). Appellants do not now state any new basis for their contention that the document was improperly admitted.

Defendants also refer to an earlier teletype dated June, 1975 (Br., p. 19, paragraph 9), from FDA headquarters to FDA's New York District Office requesting an inspection to determine the firm's compliance with the injunction. This teletype led to the July attempt to inspect, and that attempt provided the basis for the charge dismissed by the district court (A-155-164; Tr. 76-85). This document also was supplied to the defense as part of the further bill of particulars (A-32). The document was offered into evidence for the same purpose as the October, 1975, teletype and was objected to, apparently on the ground that it had not been supplied to defendants with the bill of particulars (A-157; Tr. 78). As in the case of the October, 1975, teletype, the objection was overruled, and the document was admitted into evidence (A-158; Tr. 79). Again appellants have not stated any new basis for their contention that the document was improperly admitted.

Appellants refer (Br., p. 23, first paragraph) to an admonition by the district court to the defendant, Jesse Ross to answer a question on cross-examination as to whether he thought "that the F.D.A. had the right to come in and verify that you had done [sent Diapulse machines to some experimenters to conduct experiments . . . A-229; Tr. 149] what they [the F.D.A.] had permitted you to do and no more?" [under the terms of the injunction] (A-231; Tr. 151). Although appellants apparently refer to the court's requiring Mr. Ross to answer this question as an error, no objection was raised by appellants after the district court had ruled the question relevant (A-231; Tr. 151) and no basis for error is stated in appellants' brief.

Appellants at this point in their brief also refer to the question addressed to Jesse Ross, by his counsel when he was questioned about his refusal to permit an F.D.A. inspection in 1972 and which was followed by another question concerning whether that refusal of inspection was followed by a contempt action (A-243; Tr. 163). The prosecutor properly objected to the question on the grounds of relevancy, and the objection was sustained. Appellants do not now explain the relevancy of the question nor provide any basis for their contention that the district court erred in sustaining the objection, and, indeed, this is not surprising. The question to be decided by the jury was whether or not appellants were guilty of contempts in October of 1975. Whether appellants were or were not charged with contempt in 1972 had no bearing on that issue. Finally, appellants have not indicated the way in which these rulings affected any of their substantial rights. Consequently, appellants have failed to establish that these rulings, even if they were conceded to be erroneous, were anything more than harmless error. Thus appellants have failed to justify reversal of their convictions. 28 U.S.C. § 2111; cf. *United States* v. *Birnbaum*, 373 F.2d 250 (2d Cir.), *cert. denied*, 389 U.S. 837 (1967).

POINT III

The sentence imposed by the district court was neither excessive nor erroneous.

As noted above, on August 27, 1976, the district court sentenced Jesse Ross, the president of the corporation, for his conviction on one count of violating the injunction, to a fine of $2500 (A-329); it sentenced Joseph I. Ross, the vice-president and treasurer of the corporation, to a fine of $625 on each of two counts for violating the injunction, for a total fine of $1250 (A-331); and it sentenced the corporation to a fine of $1250 on each of two counts for violating the injunction, for a total fine of $2500 (A-333). Appellants contend that the fines were excessive, arguing that 18 U.S.C. § 402 establishes a limit of $1,000 as a fine upon a natural person convicted of a contempt which is also a criminal offense under any statute. What appellants overlook, however, is that 18 U.S.C. § 402 is not applicable here, since the authority for the district court to punish for disobedience of the order involved in this action is found in 18 U.S.C. § 401. *United States* v. *Diapulse Corporation of America*, 365 F. Supp. 935 (E.D.N.Y., 1973).

Moreover, it is well established that 18 U.S.C. § 401 does not limit the sentencing power of the court; the sentence is discretionary, and the court may punish for contempt "by fine or imprisonment." The sentence is only reviewable to determine whether it is so extreme as to amount to an abuse of discretion. *Green* v. *United States*, 356 U.S. 165, 188 (1958); *United States* v. *United Mine Workers of America*, 330 U.S. 258 (1947); *United States* v. *Conole*, 365 F.2d 396 (3d Cir. 1966), *cert. denied*, 385 U.S. 1025 (1967). Here, it is clear that the sentences were entirely reasonable.

The injunction involved in this proceeding was issued under the authority of the Food and Drug Act. The Act authorizes inspections, 21 U.S.C. § 374(a), and makes it a crime to refuse to permit inspection, 21 U.S.C. § 331(f). The courts have consistently held that a factor to be considered in determining if there has been an abuse of sentencing discretion in the case of a 401 contempt which is charged as the result of a violation of a regulatory act is whether the sentence is within the maximum provided for a violation of the particular regulatory statute involved. See, e.g., *Brown* v. *United States*, 359 U.S. 41, 52 n.15 (1959); *Green* v. *United States*, *supra*, 356 U.S. at 189; *Moore* v. *United States*, 150 F.2d 323, 325-6 (10th Cir. 1945), *cert. denied*, 326 U.S. 740 (1945). The maximum penalty applicable to appellants for a violation of the Food and Drug Act was one year imprisonment and a $1,000 fine or both. 21 U.S.C. § 333(a). In addition, the district court was not limited to the maximum sentence which may be imposed for a petty offense (six months and or $500; see 18 U.S.C. § 1(3)) because the trial was to a jury. *Cheff* v. *Schnackenberg*, 384 U.S. 373 (1966).

Here, the sentence imposed on each appellant was well within the district court's discretion. Neither appellant Jesse Ross nor Joseph Ross received any jail time. The fine imposed on Joseph Ross was less than $1,000 on each count ($625); Jesse Ross received a fine of only $1500 in excess of $1,000 ($2500); and the corporation on the counts on which it was convicted received fines of only $1250 per count. Clearly these fines are reasonable and well within the Court's discretion.

CONCLUSION

For all of the foregoing reasons, the judgments of conviction should be affirmed.

Dated: November 15, 1976

Respectfully submitted,

DAVID G. TRAGER,
United States Attorney,
Eastern District of New York.

ALVIN A. SCHALL
CYRIL HYMAN
Assistant United States Attorneys

RICHARD A. MERRILL
Chief Counsel

FOREST T. PATTERSON
Associate Chief Counsel

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

DONALD I. BAKER
Assistant Attorney General
Antitrust Division

CHARLES R. MCCONACHIE
Acting Chief
Consumer Affairs Section

JOHN FLEDER
Attorney
Consumers Affairs Section
United States Department of Justice
Washington, D.C. 20530
*Of Counsel.**

---

* The United States Attorney's Office wishes to acknowledge the assistance of Marilyn Go and Karen Sclafani. Ms. Go is a third year law student at Harvard School of Law, and Mrs. Sclafani is a third year law student at New York University School of Law.

★ U. S. Government Printing Office 1976— 714—018—15

STATE OF NEW YORK
COUNTY OF KINGS
EASTERN DISTRICT OF NEW YORK } ss

LYDIA FERNANDEZ being duly sworn,

deposes and says that he is employed in the office of the United States Attorney for the Eastern District of New York.

That on the 15th day of November 19 76 he served a copy of the within

Brief for the Appellee

by placing the same in a properly postpaid franked envelope addressed to:

Copal Mintz, Esq.
150 Broadway
New York, N. Y. 10038

and deponent further says that he sealed the said envelope and placed the same in the mail chute drop for mailing in the United States Court House, Washington Street, Borough of Brooklyn, County of Kings, City of New York.

Lydia Fernandez
LYDIA FERNANDEZ

Sworn to before me this
15th day of November 19 76

Sylvia B. Morris
SYLVIA B. MORRIS
Notary Public, State of New York
No. 24-4503810
Qualified in Kings County
Commission Expires March 30, 1977